



MATERIAL OF TRADE – EXCEPTION

(Diagnostic Specimens)*

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Background. There are instances when government organizations transporting diagnostic specimens meet a U.S. Department of Transportation (DOT) exception to the DOT's Hazardous Materials Regulations (HMR). That exception is called the Material of Trade exception and it is defined in Title 49, Code of Federal Regulations (CFR), Part 171.8 as meaning "...a hazardous material that is carried on a motor vehicle...by a private motor carrier...in direct support of a principal business that is other than transportation by a motor vehicle." The specific requirements for using the Material of Trade exception are stated in 49 CFR 173.6.

Application. Diagnostic specimens are classified by the DOT as a hazardous material when transported in commerce, and normally the HMR require that they be packaged and marked as described in 49 CFR 173.199. If, however, the diagnostic specimens are transported by a "private motor carrier" for a noncommercial purpose, then the Material of Trade exception applies and would reduce the regulatory requirements that must be met.

Example. A correct and proper use of the Material of Trade exception would be to have diagnostic specimens transported in a government vehicle using a government driver from one government location (such as an off-post health clinic) to another government location (such as a government medical treatment facility or government research facility) for consolidation or accumulation with other samples generated by that facility for diagnosis or investigation, even if transported across public highways.

Specifics. The specific requirements from 49 CFR 173.6 are stated in the paragraphs below. The diagnostic specimens must be contained in combination packaging. The combination packaging has an outer packaging that is strong, securely closed, and secured against movement. The following requirements also apply:

- For liquids, the inner packaging must be leakproof, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging.
- The combination packaging must consist of one or more inner packagings each of which, when filled, does not exceed 0.5 kg (1.1 pound), or 0.5 L (17 ounces). The package for transport must weigh less than 4 kg (8.8 pounds) and/or have a capacity less than 4 L (1 gallon).
- The outer packaging must be marked with the words "Biological substance, Category B."
- The maximum total weight of all the combination packages loaded on one motor vehicle at one time for transportation cannot exceed 440 pounds.
- The operator of the motor vehicle must be informed of the presence of the hazardous material that is being transported and also must know the regulatory specifics (i.e., the ones extracted from the HMR and stated in the paragraphs above.)

* Note: The term “diagnostic specimen” was changed to “Biological substance, Category B.” This came from a final rule by the Department of Transportation on 2 June 2006, effective 1 Oct 2006.

Supporting information. The following definitions and clarifications come from various letters of interpretation that the DOT has written and from coordination with transportation experts (for hazardous materials) at Department of the Army level. These clarifications pertain directly to the definition of a private motor carrier and the transport of hazardous materials over the public highways for the accomplishment of the government mission.

- The transport of hazardous materials in military or government-owned or government-leased vehicles operated by military or government personnel solely for noncommercial purposes is not subject to the HMR.
- A private motor carrier is a carrier which transports the business’s own products and does not provide such transportation service to other businesses.
- The application of the Materials of Trade exception, as stated in this paper, does not conflict with the Defense Transportation Regulation, DOD 4500.9-R.

Important distinctions. There are some distinctions that need to be made in order to clarify the applications of the Material of Trade exceptions. In each of the following examples, the transport is considered “commercial” and **all** the applicable **rules in the HMR apply**. The Materials of Trade exceptions are not applicable and do not apply to any of the following situations (because each of these examples is considered to be “in commerce”):

- Government vehicle with government driver transports diagnostic specimens directly from the clinic to a laboratory which will analyze it under contract with the government.
- The government entity offers hazardous material for transportation to commercial carriers.
- The government vehicle is operated by a driver who is a contractor (i.e., not a government employee).

If there are questions on this matter, please contact the Hazardous and Medical Waste Program, U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD 21010-5403. Phone number: (410)436-3651.

[Back to Fact Sheet Index](#)